December 15, 2005



Office of Nutritional Products 1 0 A 6 JAN -3 P2:29 Labeling and Dietary Supplements (HFS-810)

Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

DEC 19 2005

RE 30 Day Notification of Statements on Dietary Supplement

Dear Sir or Madam,

Chattem, Inc. submits the information in this notification pursuant to 21 CFR Subpart F, section 101.93 as notice of marketing structure/function claims.

The following statements are being made for the dietary supplement Garlique® CardioAssistTM Advanced Heart Formula:

- The clinically tested Garlique® CardioAssist™ formula contains a blend of plant sterols and key vitamins important in promoting the healthy function of your heart.
- Niacin research has shown that flush-free niacin helps maintain triglyceride and HDL cholesterol levels already within a healthy range
- Vitamins B6, B12 and Folic acid work together to help maintain homocysteine levels already within a healthy range

These statements are accompanied by the required disclaimer. The information contained in this notice is complete and accurate. Chattem maintains on file substantiation that these statements are truthful and non-misleading. An original and two copies are enclosed.

Sincerely,

David W. Grob, MS, RAC

David Drut

Director, Regulatory Affairs and Safety

Chattem, Inc.

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